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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,903	02/28/2007	Tracey Jean Brown	650064.407USPC	7122

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
02/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,903	BROWN ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-22* is/are pending in the application.

4a) Of the above claim(s) *3-10 and 14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 and 12-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 11/19/2008, has been entered.

Claim 11 has been canceled.

Claims 1-10 and 12-22 are pending.

Claims 3-10 and 14-22 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions/species, there being no allowable generic or linking claim.

Claims 1-2 and 12-13 are currently under examination as they read on the elected invention drawn to an isolated compound wherein the compound is an antibody that specifically targets SEQ ID NO: 25 or a hyaluronan synthase sequence containing one or more conservative amino acid substitutions of SEQ ID NO: 25.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 11/19/2008.

The rejections of record can be found in the previous Office Action, mailed 08/19/2008.

3. Applicant's amendment to the claims, in particular changing "compound" to "antibody", filed 11/19/2008, has been acknowledged.

4. Applicant's amendment to the specification, filed 11/19/2008, has been entered.

Priority

5. The foreign priority applications, 2003905551 and 20033906658, appear to provide sufficient written support for claims 1-2 and 12-13.

Claim Rejections - 35 USC § 112 second paragraph

6. The previous rejection under 35 U.S.C. 112, second paragraph, for the recitations of "deimmunized antibody" and "or otherwise associating with HAS" has been withdrawn in view of Applicant's amendment to the claims, filed 11/19/2008.

Claim Rejections - 35 USC § 112 first paragraph

7. The previous written description rejection under 35 U.S.C. 112, first paragraph, for the recitations of "interactive molecule" and "conservative amino acid substitution" has been withdrawn in view of Applicant's amendment to the claims, filed 11/19/2008.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2 and 11-13 is rejected under 35 U.S.C. 102(b) as being anticipated by Briskin et al. (US 20020151026 A1, see entire document).

Applicant's argument has been considered in full but has not been found persuasive essentially for the reasons of record.

In response to Applicant's argument that Briskin et al. did not teach an antibody that specifically targets SEQ ID NO: 25, it is noted that Briskin's antibody reduced the level of hyaluronan synthase activity (see paragraphs 0062). Given that the prior art antibody has the same functional activity as the antibody of the present invention, it is more likely than not that the prior art antibody would bind to SEQ ID NO: 25 in order to inhibit HAS.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-2 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briskin et al. (US 20020151026 A1) in view of Falkenberg et al. (*J. Clin. Chem. Clin. Biochem*. 1984, 22:867-882) and Owens et al. (*Journal of Immunological Methods*, 1994, 168:149-165).

The teaching of Briskin et al. has been discussed above. Briskin et al. do not teach the antibody to be monoclonal, polyclonal or a humanized antibody.

Applicant's argument has been considered in full but has not been found persuasive essentially for the reasons of record.

Applicant's argument and Examiner's rebuttal are essentially the same as above. Given that the prior art antibody has the same functional activity as the antibody of the present invention, it is more likely than not that the prior art antibody would bind to SEQ ID NO: 25 in order to inhibit HAS.

Given the teaching by Briskin in using the antibody for therapeutic purposes (see paragraph [0068]), it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to make a monoclonal, polyclonal and/humanized antibody that has HAS-inhibiting activity because the antibody technology has been mature in the art as evidenced by Owens et al. and Falkenberg et al. for reasons stated in the previous Office Action, mailed 08/19/2008.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Conclusion

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
February 11, 2009

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
February 17, 2009